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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,888	10/06/2003	Nader Najafi	IB-12	3813

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EXAMINER
MALLARI, PATRICIA C

ART UNIT	PAPER NUMBER
3735	

NOTIFICATION DATE	DELIVERY MODE
06/17/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/679,888	NAJAFI ET AL.	
	Examiner	Art Unit	
	PATRICIA C. MALLARI	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,13,14,17-21,28 and 30-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,13,14,17-21,28 and 30-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 January 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The finality of the previous Office action has been withdrawn. This is a final Office action.

Response to Arguments

In the response filed 5/6/08, the applicants noted that the previous Office action failed to address the applicants' arguments in the response filed 1/25/08 with regard to Allen reference, which reference was relied upon in the rejections of claims 1-3, 6, 7, 9, 10, 13, 14, 17-19, 20, 21, and 30-33. The finality of the previous Office action has been withdrawn, and this final Office action is being issued in order to address the Allen reference.

Although new grounds of rejection are presented, some of the rejections set forth below are based on the Allen reference. Because the Allen reference is still relevant, the applicants' arguments with regard to Allen in the response filed 1/25/08 are being addressed here. With regard to the Allen reference, the applicants appear to contend that the sensor of Allen is flat, which prevents the sensor from being lodged "properly" or "properly oriented" in an artery or to block a cylindrical shaped artery in such a manner that the sensing element faces the proper direction. The applicants conclude by stating that the anchoring technique of Allen is different from that to the instant application (see pp. 25-26 of the response filed 1/25/08). However, claim 1 does *not* recite that the sensor should be lodged "properly" or that the sensor blocks an artery "in such a manner that the sensing element faces the proper direction". Claim 1 further fails to address any anchoring technique. Claim 1 merely recites, "a hermetic sensor

package adapted to be implanted into and configured to block a pulmonary artery of a patient". The sensor of Allen is of a size and shape that is capable of at least partially blocking a pulmonary artery. Col. 8, lines 51-58 of Allen describe the circular sensors as being between 0.5 to 3 cm in diameter and 0.05 to 0.30 inches in thickness. Since the sensor of Allen will take up at least some space or volume of the artery when placed within the artery, the sensor is capable of causing at least partial blockage in the artery, either during positioning of the sensor, or once the sensor is positioned to accurately sense a parameter. Furthermore, since the diameter of the sensor may be larger than a pulmonary artery, the sensor is capable of completely occluding blood flow in the artery, even if the sensor is only capable of such occlusion in a position that may not be "proper".

Of the other claims which are rejected based on the Allen reference, only claims 20 and 21 are relevant to the anchoring technique. Claim 20 merely recites, "wherein said sensor package further comprises an anchoring mechanism". Allen explicitly discloses an anchoring mechanism (see entire document, especially figs. 6 & 7; col. 14, lines 36-67 of Allen). Claim 21 recites that "said anchoring mechanism comprises a diameter of said sensor package". Allen discloses that the sensor may be 0.5 to 3 cm in diameter. Pulmonary artery may vary in diameter from patient to patient, but generally can be in the range of 1 to 3 cm (examples of disclosed diameters: 1-2.5 cm, col. 3, lines 53-64 of US Patent No. 3,66,7069 to Blackshear; 30 mm, col. 4, lines 38-41 of US Patent No. 5,895,398 to Wensel et al.; 13-18 mm, col. 5, lines 1-8 of US Patent No. 6,961,600 to Kohl et al.; up to 26 mm, col. 11, lines 8-11 of US Patent No. 7,261,732 to

Justino). Therefore, a sensor package having a diameter of 3 cm may be larger than the diameter of the pulmonary artery. If the sensor package is larger than the diameter of the pulmonary artery, then the diameter of the sensor package would be sufficient to act as an anchoring mechanism to anchor or help anchor the sensor within the artery.

With respect to the response filed 5/6/08, the applicants further remark that the sensor of Allen is initially rolled when delivered and must be unrolled when implanted and that figures 18-20 of Allen clearly show that a sensor and delivery method do not result in the artery 268 being blocked. However, as admitted by the applicants, the sensor of Allen is capable of being inserted into the artery in a rolled configuration, wherein the sensor is configured to block the artery in such a rolled configuration. In an unrolled configuration, and as shown in figures 19 and 20, the sensor package is capable of at least partially blocking the artery since the sensor package takes up space in the inside of the artery and would prevent blood flow in the space in which the sensor package is placed. Moreover, the only references to artery blockage by the sensor in the applicants' specification are on the last full paragraph of p. 11 and in figure 1. Figure 1 shows the sensor package blocking the pulmonary artery but does not show complete occlusion of the artery. The paragraph on p. 11 describes moving the implantable sensor into a pulmonary artery into a pulmonary artery until movement is prevented by the size of the pulmonary artery. Although the paragraph describes the pulmonary artery as being blocked, the paragraph does not disclose the artery as being fully occluded and further fails to state that blockage is caused by the sensor alone. In light of the applicants' disclosure, the broadest reasonable interpretation of the sensor

package being “configured to block a pulmonary artery of a patient" in claim 1 is a sensor package which results in at least partial occlusion of the artery.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the sensing device adapted to monitor at leas tone additional physiological parameter within the pulmonary artery, as claimed in claims 6 and 10; the means for monitoring patients with telephone-based or web-based data and information delivery, means for closed-loop drug delivery to treat patients with pulmonary hypertension, means for closed-loop tuning of medical systems to treat pulmonary hypertension or pulmonary hypertension related conditions, means for warning of worsening of pulmonary hypertension or pulmonary hypertension related conditions, and means for reporting global positioning coordinates for emergency applications, as claimed in claim 14; and embodiments wherein the sensor package further comprises thermal generators, voltage sources, current sources, probes, electrodes, drug delivery pumps, valves, meters, microtools for localized surgical procedures, radiation emitting source, defibrillators, muscle stimulators, and pacing stimulators, as claimed in claim 28 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate

prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, 13, 14, 17-21, 28, 30-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites, “said sensor package being formed from bonded layers of at least one of glass and silicon". The instant specification provides support for such a package being formed from bonded layers of both glass *and* silicon (see second full paragraph on p. 8 of the instant specification) but lacks support for such a sensor package being formed from bonded layers of just glass or bonded layers of just silicon.

Claim 13 recites, “The method of claim 30, wherein the method is part of at least one procedure chosen from the group" wherein the group includes "early diagnosis of pulmonary hypertension and related conditions", “treatment of complications from pulmonary hypertension related conditions", "treatment of complications from pulmonary hypertension conditions", "identification of mitral valve stenosis", and "treatment of mitral valve stenosis". While claim 13 as originally filed claimed a system used for applications including those listed above, it did not recite the method of claim 30 wherein the method is part of any of the procedures recited above, nor did claim 13 as originally filed describe how the system could be used in each recited application. Pages 2-3 of the applicants’ specification describe using the implanted sensor for a number of advantages/procedures, but not of the "procedures” recited above are included therein. Therefore, the original specification fails to provide sufficient support of the method of claim 30 being a part of any of the procedures listed above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4, 5, 7, 9, 14, 20, 21, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 56,409,674 to Brockway et al. in view of US Patent Application Publication No. 2003/0010808 to Uhland et al. Brockway discloses a system for monitoring pulmonary artery pressure within a patient, the system comprising a sensor package containing at least one sensing device 300 comprising of at least one inductor coil 310, at least one sensor 305, and optional electronic components (see entire document, especially figs. 3A; col. 6, line 66-col. 7, line 27; col. 8, lines 10-19; col. 8, line 58-col. 10, line 25 of Brockway). The sensor package is adapted to be implanted into and configured to block a pulmonary artery (see entire document, especially figs. 3A-D, 7; col. 14, lines 41-50 of Brockway) A readout device is not adapted to be implanted in the pulmonary artery and comprises at least one inductor coil having telemetric means for at least one of electromagnetic telecommunication and electromagnetic wireless powering of the sensing device through the at least on inductor coil of said sensing device (see entire document, especially col. 9, line 66-col. 10, line 25 of Brockway). Brockway lacks details as to the construction of the sensor package but does state that it is desirable to prevent entry of bodily fluids into the housing (see entire document, especially col. 9, lines 15-20 of Brockway).

However, Uhland discloses a hermetically sealed housing suitable for an implantable device, wherein the housing is formed from bonded layers of at least one of silicon 69 and glass 62 (see entire document, especially figs. 3A, 3B; paragraphs 6, 26,

and 81 of Uhland). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the type of housing described by Uhland as the housing of Brockway, since Brockway discloses using an implantable housing wherein preventing the entry of bodily fluids is desirable, and Uhland describes an appropriate such type of housing.

Regarding claim 4, the sensing device further comprises a battery (see entire document, especially col. 10, lines 1-25 of Brockway).

Regarding claim 5, wireless means are included for recharging the battery (see entire document, especially col. 10, lines 1-25 of Brockway).

Regarding claim 7, the sensor package is adapted to be implanted in the pulmonary artery to monitor pulmonary artery pressure (see entire document, especially col. 14, lines 41-50 of Brockway).

Regarding claim 9, "at least one of resonant, passive, and active means for telecommunicating and/or telepowering with said readout device" meets the three prong analysis set forth in MPEP 2181, thereby invoking 35 U.S.C. 112, 6th paragraph. The corresponding structure for such passive means set forth in the applicants' specification include devices that have on-board circuitry but still receive their operating power from an external source (passive device 201; see p. 5 of the instant specification). The corresponding structure for such active means is one in which a power-storage element allows the implant to function without requiring the immediate presence of the readout unit as a power supply (see p. 8 of the instant specification) Brockway, as modified, includes embodiments using either a device that has on-board

circuitry and still receives its operating power from an external source or a device having a rechargeable power-storage device which does not require the immediate presence of the readout unit as a power supply (see entire document, especially col. 9, line 66-col. 10, line 25).

Regarding claim 14, the language "means for at least one of: remote monitoring of patients with pulmonary hypertension" meets the three prong analysis set forth in MPEP 2181, thereby invoking 35 U.S.C. 112, 6th paragraph. Although the applicants have not explicitly identified the corresponding structure, the corresponding structure set forth in the applicants' specification appears to be merely a device which enables remote monitoring or delivery of information from the implanted sensing device using wireless communication (see pp. 8-9 of the instant specification). Brockway discloses a device which enables remote monitoring using wireless communication (see entire document, especially fig. 2; col. 9, line 45-col. 10, line 25 of Brockway)

Regarding claim 20, the sensor package further comprises an anchoring mechanism 312A-D (see entire document, especially figs. 3A-D of Brockway).

Regarding claim 21, the anchoring mechanism comprises a diameter of the sensor package (see entire document, especially figs. 3A-D of Brockway), wherein the diameter of the sensor package is capable of being used to anchor the device. Alternatively, stabilizer 312D is a portion of the sensor package and the diameter of the entire package, including the stabilizer, functions to anchor the device in place (see entire document, especially fig. 3D; col. 8, lines 38-57 of Brockway).

Regarding claim 32, at least a portion of the sensor package 300 is coated with at least one layer of coating (see entire document, especially col. 13, lines 49-53 of Brockway).

Claims 1, 3, 6, 7, 9, 10, 14, 20, 21, 32, and 33 are rejected under 35 U.S. C. 103(a) as being unpatentable over US Patent No. 7,147,604 to Allen et al. in view of US Patent Application Publication No. 2003/0010808 to Uhland et al. Allen discloses a system for monitoring pulmonary artery pressure comprising a hermetic sensor package adapted to be implanted into and configured to block a pulmonary artery of a patient (see entire document, especially col. 3, lines 63-65; col. 7, lines 40-48 of Allen). The package contains at last one sensing device comprising at least one inductor coil and at least one sensor, with optional electronic components (see entire document, especially figs. 2, 5, 8; col. 8, lines 30-39; col. 9, line 1-col. 10, line 20; col. 10, lines 34-44; col. 11, lines 4-16 of Allen). A readout device that is not adapted to be implanted in the pulmonary artery comprises at least one inductor coil having telemetric means for at least one of electromagnetic telecommunication and electromagnetic wireless powering of the sensing device through the at least one inductor coil of the sensing device (see entire document, especially col. 10, lines 1-20; col. 14, lines 36-67; col. 15, line 21-col. 16, line 12 of Allen). Allen lacks the sensor package being formed from bonded layers of at least one of glass and silicon.

However, Uhland discloses a hermetically sealed housing suitable for an implantable device, wherein the housing is formed from bonded layers of at least one of

silicon 69 and glass 62 (see entire document, especially figs. 3A, 3B; paragraphs 6, 26, and 81 of Uhland). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the type of housing described by Uhland in place of or in addition to the coating used to provide the hermetic seal of Brockway, as it would merely be the substitution of one means of ensuring a hermetic seal for another or would further ensure that no bodily fluids can enter the cavity or cavity material can exit the sensor.

Regarding claim 3, the sensing device comprises at least one capacitive sensor (see entire document, especially col. 9, lines 10-11 of Allen).

Regarding claims 6 and 10, the sensing device is adapted to monitor at least one additional physiological parameter (see entire document, especially col. 3, lines 55-58; col. 4, lines 43-60; col. 10, lines 21-28 of Allen). With further regard to claim 10, the at least one additional physiological parameter is temperature (see entire document, especially col. 3, lines 55-58; col. 4, lines 43-60; col. 10, lines 21-28 of Allen).

Regarding claim 7, the sensor package is adapted to be implanted in the pulmonary artery to monitor pulmonary artery pressure (see entire document, especially col. 7, lines 39-48 of Allen).

Regarding claim 9, the language “resonant, passive, and active means for telecommunicating and/or telepowering with said readout device" meets the three prong analysis set forth by MPEP 2181, thereby invoking 35 U.S.C. 112, 6th paragraph. The corresponding structure set forth in the applicants' specification for the resonant means is one which consists of only a packaged inductor coil and a capacitive pressure sensor

(see p. 4 of the instant specification). Allen, as modified, discloses such a resonant means consisting of only a packaged inductor coil and a capacitive pressure sensor (see entire document, especially figs. 1-5, 8; col. 8, lines 31-39; col. 9, lines 1-55 of Allen).

Regarding claim 14, the language "means for . . . monitoring of patients with pulmonary hypertension with web-based data and information delivery" meets the three prong analysis set forth in MPEP 2181, thereby invoking 35 U.S.C. 112, 6th paragraph. The corresponding structure set forth in the applicants' specification appears to be a system implemented as a remote monitoring configuration including wireless or web-based delivery of information received from the implant by the reader to a physician or caregiver (see pp. 8-9 of the instant specification). Allen, as modified, describes such a system including wireless and web-based delivery of information received from the implant (see entire document, especially col. 14, lines 36-67 of Allen).

Regarding claim 20, the sensor package further comprises an anchoring mechanism (see entire document, especially figs. 6 & 7; col. 8, lines 59-67 of Allen).

With further regard to claim 21, the anchoring mechanism may be the diameter of the sensor package, wherein the diameter of the package is such that it is capable of anchoring the package (see entire document, especially figs. 1-5; col. 8, lines 51-59 of Allen), particular when the package is implanted in a vessel having a diameter which is almost the same as that of the package.

Regarding claims 32 and 33, at least a portion of the sensor package is coated with at least one layer of coating (see entire document, especially col. 10, lines 29-44;

col. 13, lines 61-67 of Allen). With further regard to claim 33, the coating material is silicone (see entire document, especially col. 13, lines 61-67 of Allen).

Claims 2, 13, 17, 18, 19, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen in view of Uhland, as applied to claims 1, 3, 6, 7, 9, 10, 14, 20, 21, 32, and 33, and further in view of US Patent No. 4,869,263 to Segal et al. Regarding claim 30, Allen, as modified, discloses injecting the sensor package for heart pressure measurement in a patient's pulmonary artery (see entire document, especially col. 3, lines 63-65 of Allen) and further discloses delivering the sensor package by injecting it so as to lodge the sensor package into a blood vessel (see entire document, especially col. 7, lines 39-48 of Allen). Allen lacks the blood flow through a first pulmonary artery delivering the sensor package from a first pulmonary artery and anchoring it into a second pulmonary artery with a smaller diameter than the first pulmonary artery.

Segal et al. discloses positioning an implant in a pulmonary artery 131 by implanting the device so as to deliver it into a first pulmonary artery 129, wherein the blood flow through the first pulmonary artery 129 delivers and anchors (lodges or wedges) the device into the second or distal pulmonary artery 131 and wherein the diameter of the distal or second pulmonary artery 131 is shown in figure 11 as being smaller than that of the main or first pulmonary artery 129 (see entire document, especially fig. 11; col. 5, lines 42-66 of Segal). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the method of Segal

with that of Allen, as modified, since Allen discloses injecting the sensor for pressure measurement in a pulmonary artery and Segal describes an appropriate way of delivering a medical device to the pulmonary artery, for the predictable result of delivering and anchoring the sensor package in a pulmonary artery.

Regarding claim 2, implantation of the sensor package is performed for diagnosis of hypertension, wherein clearly, if the pulmonary arterial pressure is being monitored, then the determination of hypertension based on such a pressure is of pulmonary hypertension (see entire document, especially col. 1, lines 15-64 of Allen).

Regarding claim 13, the method is part of disease management (see entire document, especially col. 1, lines 15-65 of Allen).

Regarding claim 17, the injection of the sensor package into the pulmonary artery or similar vessel is a surgical technique (see entire document, especially col. 3, lines 63-65; col. 7, lines 39-48 of Allen; col. 5, lines 42-66 of Segal).

Regarding claim 18, the injection of the sensor package is a minimally invasive outpatient technique (see entire document, especially col. 3, lines 63-65; col. 7, lines 39-48 of Allen; col. 5, lines 42-66 of Segal).

Regarding claim 19, a catheter delivery technique is used to inject the sensor package (see entire document, especially col. 3, lines 63-65; col. 6, line 31-col. 7, line 48 of Allen).

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway in view of Uhland, as applied to claims 1, 4, 5, 7, 9, 14, 20, 21, and 32 above.

Brockway, as modified, discloses that the communication circuit 310 may include a microprocessor or other circuit for performing data analysis (see entire document, especially col. 9, lines 45-63 of Brockway) but is silent as to the details of the data analysis. Brockway further discloses that the determination of dP/dt is useful in monitoring the work load of the heart (see entire document, especially col. 1, line 38-col. 2, line 6 of Brockway). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention for the data analysis of the microprocessor of Brockway, as modified, to determine dP/dt, since Brockway discloses a microprocessor that performs data analysis and Brockway further describes analyzing the pressure signal to determine dP/dt, wherein dP/dt is useful in determining the work load of the heart, among other things.

The language “means for calculating changes in said pulmonary artery pressure over time dp/dt" meets the three prong analysis set forth in MPEP 2181, thereby invoking 35 U.S.C. 112, 6th paragraph. The corresponding structure disclosed in the originally filed disclosure appears to be merely the structure recited in claim 8 as originally filed: "said system calculates the change of pressure over time, dp/dt". Brockway, as modified above, discloses such a system that calculates the change of pressure over time dp/dt.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway in view of Uhland, as applied to claims 1, 4, 5, 7, 9, 14, 20, 21, and 32 above, and further in view of US Patent No. 6,636,769 to Govari. Brockway, as modified, lacks

any of the devices recited in claim 28, including a radiation emitting source. However, Govari discloses an implantable pressure sensing device, wherein the sensing device comprises an induction coil 68 and a pressure sensor 52, 56, 90, 92, 100, wherein the pressure sensor further comprises a radiation emitting source 100 (see entire document, especially fig. 5; col. 5, line 49-col. 6, line 30; col. 6, line 66-col. 7, line 48; col. 9, lines 6-30 of Govari). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the pressure sensor of Govari in place of that of Brockway, as it would merely be the substitution of one known implantable pressure sensor for another.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Allen in view of Uhland and Segal, as applied to claims 2, 13, 17, 18, 19, and 30 above, and further in view of US Patent No. 5,662,712 to Pathak et al. Allen, as modified, lacks cell growth and encapsulation of the sensor package to stabilize the senor package. However, Pathak discloses a device implanted in an artery, wherein cell growth and encapsulation of the device are encouraged to stabilize/anchor the device (see entire document, especially col. 6, lines 1-24 of Pathak). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to include cell growth and encapsulation as shown in Pathak in the method of Allen, as modified, in order to further stabilize or anchor the sensor.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PATRICIA C. MALLARI whose telephone number is (571)272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/
Examiner, Art Unit 3735